

REMARKS

As a result of the foregoing amendment, Claim 1 has been cancelled and replaced with new Claim 26. Claims 2-5 and 10-22 have been cancelled without prejudice. Claims 6, 9 and 23 have been amended to depend from new Claim 26, Claim 7 has been amended to depend from new Claim 30, and Claim 8 has been amended to depend from new Claim 34. New Claims 27-34 have been added. New Claim 26 recites that the recited catheter shaft is an "indwelling" shaft as described at page 2, paragraphs [00004] and [00005], as well as [00014]. New Claim 26 further defines the invention as being composed of a proximal tube segment composed of a first polymer material of a first durometer, a distal tube segment containing a second polymer material of a second durometer, wherein the proximal tube segment is stiffer than the distal tube segment and a transition tube segment interposed between the proximal tube segment and the distal segment, the transition tube segment being composed of both the first polymer material and the second polymer material. Additionally, in the transition tube segment, the amount of the second polymer material continually decreases from the distal tube segment to the proximal tube segment and the amount of the first polymer material continually increases from the distal tube segment to the proximal tube segment. New claim 26 also incorporates the recitation of cancelled claim 5 that the durometer of the polymer material contained in the transition tube segment continually decreases from the proximal end of the transition tube segment to the distal end of the transition tube segment. Moreover, the catheter shaft is recited as being of a non-reinforced single layer unitary construction, the proximal, distal and transition tube segments together defining an integrally formed tube in accordance with original Claim 16, now cancelled. See also the specification at page 7, paragraphs [00029] and [00030], page 12, paragraph [0042] and page 13, paragraph [00045]. New Claim 27 finds basis at page 7, paragraph [00030], Claim 28 finds basis at page 7, paragraph [00030], Claims 29 and 30 find basis at paragraph [00045] on page 13, Claims 31-33 find basis at paragraph [00034] bridging pages 8 and 9 of the specification and Claim 34 finds basis at page 13, paragraph [00047]. Additionally, new Claim 26 also recites that the catheter shaft is non-reinforced as disclosed in the drawings.

Also, new Claim 35 has been added which recites that the majority of the shaft consists of the transition segment and new Claim 36 has been added which recites that the length of the transition segment is short relative to the lengths of the distal and proximal segments in accordance with paragraph [00049] of the specification.

Reconsideration and withdrawal of the rejection of the claims as amended under 35 U.S.C. §102(b) as being anticipated by the Dinh, et al. U.S. Patent No. 6,042,578 (the '578 patent) are requested. Original Claim 5 was not included in this rejection. Inasmuch as the main independent claim, new Claim 26, contains the recitation previously contained in Claim 5, it is clear that the anticipation rejection is no longer warranted and should be withdrawn.

Turning to the rejection of the claims under 35 U.S.C. §103(a) over the Dinh, et al. '578 patent, this rejection should also be withdrawn. The Examiner asserts that the reference meets the claimed limitations discussed in connection with the rejection under 35 U.S.C. §102 except for the specific durometer and radiopaque changes within the transition tube segment. The Examiner asserts that the Dinh, et al. reference discloses a transition tube segment 80 composed of different durometer plastics and filler and refers to column 5. However, at column 5, beginning at line 51, the reference states that the guiding catheter 10 may have a stem 80 located between the body stock 20 and the soft tip 30. It then states that stem 80 is composed of a stem transition sleeve 51 and a stem sleeve 52. Thereafter, at lines 53-55, it states that the stem transition sleeve 51 is formed from 38D to 55D polyester elastomer. At lines 56-57, it states that stem sleeve 52 is formed from 38D to 55D polyester elastomer. However, there is no disclosure or suggestion in the reference that the stem 80 is formed from an elastomer of more than one durometer. Contrary to the Examiner's assertion, there is no disclosure or suggestion in this reference that stem 80 is formed from a mixture of plastics of differing durometer. The clear import of this section of the reference is that the stem may be composed of an elastomer having a durometer of between 38D to 55D. This certainly is not a suggestion that a mixture of plastics of different durometer could or should be used.

The Examiner then further concludes that it would be obvious to one having ordinary skill in the art at the time the invention was made to construct the transition tube segment of Dinh, et al. as presently claimed to achieve a good transition between the distal and proximal tube segments. However, the reference is devoid of any suggestion of a "good transition" nor is there any indication as to what the Examiner means by a "good transition" between the distal and proximal tube segments. Most certainly, the reference is devoid of any information which could be construed as disclosing or suggesting a transition tube segment composed of first and second polymer materials in which the second polymer material of the transition tube continually decreases from the distal tube segment to the proximal tube segment and the amount of the first polymer material continually increases from the distal tube segment to the proximal tube segment and wherein the durometer of the polymer material contained in the transition tube segment continually decreases from the proximal end of the transition tube segment to the distal end of the transition tube segment as required by the amended claims.

It is further clear from the disclosure at column 4, line 53 of the reference that the body stock 20 is formed from an inner liner 21, and requires an intermediate wire mesh braid 22 as a metal reinforcing element. The present claims specifically recite that the catheter shaft of the present invention is a non-reinforced single layer unitary construction and that the proximal, distal and transition tube segments together define a single integrally formed tube. There is no suggestion in Dinh et al. that one could or should indiscriminately do away with the metallic reinforcing braid. Consequently, one of ordinary skill in this art upon reading Dinh, et al. would find no reason to go against the specific teaching of Dinh, et al. that a metallic reinforcing braid is required. Accordingly, the reference teaches away from the presently claimed invention.

Furthermore, the single unitary construction recited in the claims is important, in particular for high pressure injections (CT). Thus, a unitary construction has more structural integrity than a multi-layer catheter shaft with multiple weld joints and layers as disclosed at [00048] of the specification. The Dinh reference at column 6, step 4, states that the butt joints of the various tubes are heat welded together. The present

invention teaches away from such an embodiment since the joints are weaker than a unitary construction tube and may be prone to bursting under high pressures.

The case of *In re Leshin*, 125 USPQ 416 (CCPA 1960) cited by the examiner is not in point. The invention as recited in the present claims is not based on the selection of a material on the basis of its suitability for the intended use. Rather, as is clear from the claims as amended, the present invention involves the mixing of two different polymers in increasing and decreasing amounts as one proceeds from the distal tube segment of the transition tube to the proximal tube segment. There is nothing in the claims relating to the selection of a specific polymer for a specific purpose. The Court in *Leshin* only held that mere selection of a known plastic to make a container-dispenser of a type made of plastic when the selection of the plastics are on the basis of the suitability for the intended use is obvious. However, this holding is irrelevant to the present invention as claimed. Accordingly, this rejection is also untenable and should be withdrawn.

In view of the foregoing, it is submitted that this application with the claims as amended is in condition for allowance and favorable reconsideration and prompt Notice of Allowance are earnestly solicited.

Respectfully submitted,

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